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PPLICATION NO. FILING DATE F		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,891	08/30/2001	Kenneth J. Gruys	11899.0155.DVUS02 (MOBT:1	1012
759	90 01/29/2004	EXAMINER		
Patricia A. Kai	nmerer, Esq. ON ARNOLD & WHITI	KRUSE, DAVID H		
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Houston, TX 7		1638		
			DATE MAIL ED: 01/29/2004	1

Please find below and/or attached an Office communication concerning this application or proceeding.

*			Application No.	Applicant(s)				
Office Action Summary		09/942,891	GRUYS ET AL.					
		Examiner	Art Unit	T				
			David H Kruse	1638				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status								
	Responsive to communication(s) file	d on <i>24</i> Od	tober 2003.					
			action is non-final.					
/	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims								
<ul> <li>4)  Claim(s) 42-46 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 42-46 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>								
Application Papers								
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>								
Priority under 35 U.S.C. §§ 119 and 120								
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> <li>13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.</li> <li>37 CFR 1.78.</li> <li>a) The translation of the foreign language provisional application has been received.</li> <li>14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.</li> </ul>								
Attachmen			_					
2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (P nation Disclosure Statement(s) (PTO-1449) Pa		5) Notice of Infor	mary (PTO-413) Paper No mal Patent Application (PT				

Application/Control Number: 09/942,891 Page 2

Art Unit: 1638

### **DETAILED ACTION**

### Election/Restrictions

1. Applicant's election of Group II, claims 42-46 in the response filed 24 October 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

- 2. Claim 41, directed to a non-elected invention has been cancelled.
- 3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

### Information Disclosure Statement

4. The information disclosure statement filed 30 August 2001 has been considered, a signed copy is attached hereto. Item C1 has been crossed out because while it has been considered, unpublished information is not a proper reference to be published on the face of the patent.

#### Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR § 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective

because prior application information claiming priority under 35 USC §§ 120 and 121 is incorrect or incomplete. Appropriate correction is required.

### Specification

- 6. The abstract of the disclosure is objected to because it is not specifically directed to the claimed subject matter and it too lengthy, see 37 CFR § 1.72(b). Correction is required. See MPEP § 608.01(b).
- 7. The disclosure is objected to because of the following informalities: The first line of the specification as amended on 30 August 2001 is objected to because said line should indicate that Application 09/313,123 is now abandoned, and the parentheses should be deleted. Appropriate correction is required.

# Claim Rejections - 35 USC § 101

8. 35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 42 and 46 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

At claim 42, there is no indication of the hand of man in the claim, and "A nucleic acid sequence" is information and not a composition of matter and thus does not constitute patentable subject matter. Amending the claim to recite -- An isolated or recombinant nucleic acid -- would obviate this rejection as directed to claim 42.

At claim 46, there is no indication that the claimed plant is produced by the hand of man and reads on a product of nature, which is non-statutory subject matter.

Art Unit: 1638

# Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 42-46 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claims 42-46, the limitations "at amino acid position 447" and "at amino acid position 481" are relative limitations which render the claim indefinite and thus do not state the metes and bounds of the claimed invention.

At claims 42-46, the phrase "effective to catalyze the conversion of threonine to  $\alpha$ -ketobutyrate" renders the claims indefinite because it is unclear what the metes and bounds of "effective" are.

Claim 44 is indefinite because it is unclear if the claimed recombinant host cell has been transformed with a nucleic acid encoding a threonine deaminase protein or inherently comprises said protein with the claimed properties, hence the metes and bounds of the claim are unclear.

Claim 46 is indefinite because it is unclear if the claimed plant has been transformed with a nucleic acid encoding a threonine deaminase protein or inherently comprises said protein with the claimed properties, hence the metes and bounds of the claim are unclear.

Art Unit: 1638

## Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

13. Claims 42-45 are rejected under 35 U.S.C. § 102(b) as being anticipated by Samach *et al.* 1991 (Proc. Natl. Acad. Sci. USA 88:2678-2682).

Samach *et al* disclose a nucleic acid isolated from *Lycopersicon esculentum* encoding a threonine deaminase protein that catalyzes the conversion of threonine to  $\alpha$ -ketobutyrate encoding a valine at position 481, relative to the *E. coli* threonine deaminase protein (Figure 4 on page 2680). Samach *et al* disclose a recombinant vector, a recombinant host cell and a method of preparing recombinant host cells useful to convert threonine to  $\alpha$ -ketobutyrate comprising said isolated nucleic acid (page 2681, right column). Hence, all of the claim limitations have been previously disclosed by Samach *et al*.

14. Claims 42-46 are rejected under 35 U.S.C. § 102(b) as being anticipated by Colau *et al* 1987 (Molecular and Cellular Biology 7(7): 2552-2557).

Art Unit: 1638

Colau *et al* disclose a nucleic acid isolated from *Saccharomyces cerevisiae* encoding a threonine deaminase protein that catalyzes the conversion of threonine to  $\alpha$ -ketobutyrate encoding a valine at position 481, relative to the *E. coli* threonine deaminase protein (Figure 2 on page 2554). Colau *et al* disclose a recombinant vector, a recombinant host cell, a method of preparing recombinant host cells useful to convert threonine to  $\alpha$ -ketobutyrate and a transformed plant the genome of which comprises said isolated nucleic acid (pages 2554-2556). Hence, all of the claim limitations have been previously disclosed by Colau *et al*.

15. Claims 42-45 are rejected under 35 U.S.C. § 102(e) as being anticipated by Hashiguchi *et al* (U.S. Patent 5,998,178, published 7 December 1999, filed 26 May 1995).

Hashiguchi *et al* disclose a nucleic acid isolated produced *E. coli* encoding a threonine deaminase protein that catalyzes the conversion of threonine to  $\alpha$ -ketobutyrate encoding a proline at position 447 (see column 3, 2<sup>nd</sup> paragraph and SEQ ID NO: 1 at column 35). Hashiguchi *et al* disclose a recombinant vector, a recombinant host cell, and a method of preparing recombinant host cells useful to convert threonine to  $\alpha$ -ketobutyrate comprising said isolated nucleic acid (see columns 25-32). Hence, all of the claim limitations have been previously disclosed by Hashiguchi *et al*.

### Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

Art Unit: 1638

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 42-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7 and 19 of U.S. Patent No. 5,942,660. Although the conflicting claims are not identical, they are not patentably distinct from each other because the transformed plant at claims 1 and 7 and the isolated DNA molecule at claim 19 render obvious the claims nucleic acid, recombinant vector, recombinant host cell and plant and method of making a recombinant host cell of the instant application.

Art Unit: 1638

#### Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.

26 January 2004